

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

MICROBIX BIOSYSTEMS, INC.,

Plaintiff

v.

**NOVARTIS VACCINES AND
DIAGNOSTICS, INC.,**

Defendant

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**No. 6:14-cv-3-JDL
Jury Trial Demanded**

MEMORANDUM OPINION AND ORDER

This opinion construes United States Patent No. 7,270,990 (the “’990 patent”). Plaintiff Microbix Biosystems, Inc. (“Microbix”) filed an Opening Claim Construction Brief (Doc. No. 68). Defendant Novartis Vaccines and Diagnostics, Inc. (“Novartis”) filed a Responsive Claim Construction Brief (Doc. No. 70). Microbix filed a Reply Brief (Doc. No. 72). Additionally, the parties submitted a Joint Claim Construction Chart. A Markman hearing was held on January 15, 2015.

THE ’990 PATENT

Plaintiff brings suit alleging infringement of the ’990 patent by Defendant’s process of making its AgriFlu influenza vaccine. Specifically, Microbix asserts independent claims 1 and its dependent claims 3, 6-12, 15, and 18 and independent claim 37 and its dependent claim 39. Claim 1 and its dependent claims require the step of “adding one or more salts to the allantoic fluid to generate a total salt concentration therein of greater than 0.5 M thereby dissociating virus from the debris.” See Doc. 1-1 at 18:25-29.

The application leading to the '990 patent was filed on June 18, 2004 and is based on a series of provisional applications with an earliest filing date of June 20, 2003. The '990 patent issued on September 18, 2007 and is entitled "Virus Production." The '990 patent relates to a process of recovering a virus that is grown in the allantoic fluid of chick eggs by the addition of one or more salts to the allantoic fluid. In the claimed process, salt is added to fluid harvested from the interior of the egg, known as "allantoic fluid," resulting in a total salt concentration greater than 0.5 molar. "Molar" concentration, abbreviated as "M," reflects number of moles—i.e., the number of molecules—of a substance per liter of liquid. Doc. No. 41-1 at 2-3. When a virus is grown in the allantoic fluid of chick embryos, some of the virus associates with debris in the allantoic fluid (debris-bound virus). The '990 patent teaches a technique to separate the debris-bound virus from the debris to increase the yield of virus obtained from each egg. The Abstract of the '990 patent states:

An improved process for recovery of virus from allantoic fluid of virus-infected chick embryos. Virus associated with granular and fibrous debris in the allantoic fluid can be disassociated from the debris and recovered, thereby increasing viral yield. Dissociation can be achieved by subjecting the virus-debris complex to conditions of increased salt concentrations, e.g., 0.5 M or greater.

Id. Claim 1 of the '990 patent is representative of the patent's subject matter and is shown below:

A process for recovering virus from debris-containing allantoic fluid of virus-infected chick embryos, comprising the steps of:

- (a) adding one or more salts to the allantoic fluid to generate a total salt concentration therein of greater than 0.5 M thereby dissociating virus from the debris; and
- (b) recovering virus dissociated from debris and solubilized in the allantoic fluid.

Id. Claim 37 requires the total salt concentration in step (a) to be "1.0 M or greater." *Id.* at 20:25-28.

LEGAL STANDARD

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In claim construction, courts examine the patent’s intrinsic evidence to define the patented invention’s scope. *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, a term’s context in the asserted claim can be very instructive. *Id.* Other asserted or unasserted claims can also aid in determining the claim’s meaning because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term’s meaning. *Id.* For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id.* at 1314-15.

Claims “must be read in view of the specification, of which they are a part.” *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995)). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the

single best guide to the meaning of a disputed term.” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor’s lexicography governs. *Id.* Also, the specification may resolve ambiguous claim terms “where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.” *Teleflex, Inc.*, 299 F.3d at 1325. But, “although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.” *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998); *see also Phillips*, 415 F.3d at 1323. The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc., v. Lifescan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) (“As in the case of the specification, a patent applicant may define a term in prosecuting a patent.”).

Although extrinsic evidence can be useful, it is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining

the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition is entirely unhelpful to a court. *Id.* Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.*

CLAIM CONSTRUCTION

After various concessions during the briefing, there are two separate terms that are left to be construed: "total salt concentration therein" and "salts." Many previously disputed terms were agreed by the parties during briefing. Appendix B lists these terms with the agreed constructions.

A. "total salt concentration therein"

Microbix proposes "total salt concentration in or within a volume of the allantoic fluid that need not be the total volume." P.R. 4-5(d) Chart. Novartis proposes "total amount of salt (in moles), whether added or intrinsic, in the total volume of allantoic fluid after the addition of one or more salts." The parties agree that the meaning of "total salt" is "total amount of salt in moles whether added or intrinsic." *See* Doc. No. 68 at 5. However, the parties dispute whether the relevant volume in determining concentration is the total volume of allantoic fluid, or whether the relevant volume can be any portion, however small, of the allantoic fluid surrounding the virus-debris complex where the virus is dissociated from debris.

Plaintiff argues that the constituent terms "total salt" and "concentration" should be construed separately and not the entire phrase "total salt concentration therein." *See, e.g., Doc. No. 68* at 5-8. Plaintiff argues that "total" modifies "salt" and not the word "concentration" and that "total salt" should include any added or intrinsic salt. *Id.* at 5. Plaintiff argues that for "concentration," the invention of the '990 patent is a process for increasing the yield of virus

grown in the allantoic fluid of chick embryos by dissociating virus from debris through the addition of one or more salts. *Id.* at 6. That dissociation is accomplished by creating conditions or an environment, within the allantoic fluid for a period of time, that subject the debris-bound virus to increased salt concentrations. *Id.* Plaintiff cites to various portions of the specification that allegedly support its construction. *See e.g.*, '990 patent, Abstract ("Dissociation can be achieved by subjecting the virus-debris complex to conditions of increased salt concentrations."); *Id.* at col 6:5-11 ("A preferred method of dissociating virus from the aggregate debris is to place the virus associated with the debris in an environment having a non-isotonic salt concentration. The environment is said to have a 'non-isotonic' salt concentration when it differs significantly from that of allantoic fluid . . . "); *Id.* at col. 6:33-38 ("Once virus dissociation occurs, the virus containing solution could be diluted, e.g. rendered more isotonic . . . again, prior to recovering the virus.").

Given the purpose and context of the invention, Plaintiff asserts that its construction is warranted. *Id.* at 7. In order to meet that purpose, the needed elevated salt concentration is created in conditions or environments around the debris. *Id.* Thus, the salt concentration of concern is not just the salt concentration "after the addition of one or more salts," but one when the invention achieves its purpose, namely, at the particular time and location where the virus separates from the debris. *Id.*

Plaintiff argues that Defendant's construction for "total salt concentration therein" impermissibly requires a "total volume" and limits the claims to a preferred embodiment. *Id.* at 8. Plaintiff also argues that Defendant's construction inappropriately construes "total" to modify both "salt" and "concentration." *Id.*

Claim 1 of the '990 patent provides substantial guidance in determining the meaning of the disputed term. It states “adding one or more salts to the allantoic fluid to generate a *total salt concentration therein* of greater than 0.5M.” *Id.* at 18:25-28 (emphasis added). The claim then goes on to state that the concentration dissociates virus from the debris.

The meaning of “total salt concentration” is largely dependent upon the meaning of “therein.” If “therein” can be applied to solely a small portion of the allantoic fluid or virus-debris complex, then the “total salt concentration” is not a measurement of the entire volume of the allantoic fluid. On the other hand, if “therein” is applied only to the entire volume of allantoic fluid, then the “total salt concentration” would be based upon the entire volume of the allantoic fluid.

The claim does not expressly apply the measurement of concentration to the “total volume.” However, the claim also does not mention a “virus-debris complex” or state that the volume of relevance is around a virus-debris complex. At best, in the preamble of the claim, the allantoic fluid is stated to be “debris-containing allantoic fluid,” and the generated salt concentration of step (a) dissociates virus from that debris. Contrary to Plaintiff’s arguments, however, the fact that the total salt concentration dissociates virus from the debris does not dictate or suggest that the volume of relevance is only that of the fluid around the virus-debris complex. The claim language does not mention or suggest “local” high salt concentrations or focus on total salt concentrations around a virus-debris complex even if those local concentrations help de-associate virus from the debris. A plain reading of “adding one or more salts to the allantoic fluid to generate a total salt concentration therein” is that the total salt concentration is generated in the total amount of allantoic fluid, not some undefined portion. Had the applicant wanted to claim a measurement of salt concentration in only a portion of the

allantoic fluid or at a specified time and location where the virus separates from the debris, it could have done so. Instead, the applicant selected the words “allantoic fluid.” As such, a plain reading of the claim language supports Defendant’s proposed construction.

Both parties rely on the specification in support of their arguments. Most, if not all, of the specification supports Defendant’s construction. The examples mentioned in the specification discuss calculating the total volume of the allantoic fluid, not just a portion thereof or a small portion around a virus-debris complex, to determine the salt concentration. *See*, ’990 patent, Example 2, col. 11:20-54; col. 4:49-51; col. 7:14-19. These portions of the specification are consistent with a plain reading of the claim language. Plaintiff, on the other hand, relies upon the following portion of the specification:

A preferred method of dissociating virus from the aggregated debris is to place the virus associated with the debris in an environment having a non-isotonic salt concentration. The environment is said to have a “non-isotonic” salt concentration when it differs significantly from that of allantoic fluid, which has a total salt concentration of about 150 mM.

’990 patent, col. 6:5-11. This section of the specification does not dictate or suggest that the volume for determining the necessary salt concentration is only the specific volume around the virus-debris complex. Rather, it describes how the virus dissociates from debris. Furthermore, this specification reference does not mention adding one or more salts to the allantoic fluid to generate a total salt concentration or that salts are added to a specific or local portion of an allantoic fluid. It merely mentions placing the virus in a salt concentration that is a non-isotonic salt concentration (that is, a salt concentration that differs significantly from allantoic fluid). ’990 Patent, col. 6:9-10. The Abstract is similarly unhelpful for Plaintiff. The Abstract mentions that “dissociation can be achieved by subjecting the virus-debris complex to conditions of increased salt concentration.” *Id.* Again, this language describes how dissociation operates. In other words, it describes how the virus-debris complex is disassociated by increased salt concentration.

It does not suggest that the only relevant volume for determining the required salt concentration is a specified volume around the virus-debris complex at the moment of dissociation. Overall, the specification is consistent with Defendant's construction.

Finally, the extrinsic evidence supports Defendant's proposed construction. In some cases, "the district court will need to look beyond the patent's intrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharmaceuticals U.S.A., Inc. v. Sandoz, Inc.*, — U.S. —, —, —, 135 S.Ct. 831, 841, — L.Ed.2d —, — (2015). "'Experts may be examined to explain terms of art, and the state of the art, at any given time,' but they cannot be used to prove 'the proper or legal construction of any instrument of writing.'" *Id.* (quoting *Winans v. New York & Erie R. Co.*, 62 U.S. 88, 100-01 (1859)). The declaration provided by the Defendant's expert provides relevant information regarding the background science and understanding of the term "concentration" in the relevant art of the invention.¹ Defendant's expert disclosure is consistent with the claim language and specification. Microbix did not submit contrary expert testimony.

Defendant's expert asserts that units of concentration are expressions of proportions. That is, concentration is expressed in terms of an amount of a substance in a given volume. Further, "[i]t is common knowledge in the field of chemistry that molarity is a unit of concentration which corresponds to the proportion of moles per liter." Declaration of Dr. Cummings, Doc. No. 70-2 at ¶36. The language in the patent claims expresses the amount of

¹ At the January 15, 2015 hearing Microbix implied that Dr. Cummings was not qualified to opine on the understanding of an ordinarily skilled artisan for this claim construction because he is not an analytical chemist. Hr'g at 10:42:30. The relevant inquiry, however, is into the understanding of a person of ordinary skill in the art of the invention. The present invention relates to the recovery of virus from allantoic fluid of virus-infected chick embryos to facilitate the production of viral vaccines vaccine. Dr. Cummings has a Ph.D. in Biology/Biochemistry and has held various professional and academic positions in the field of glycobiology. See Declaration of Dr. Cummings, Doc. No. 70-2 at ¶¶3-9. As such, he is qualified to opine on the understanding of a person of ordinary skill in the art as it relates to terms in the patent at issue.

salt in terms of concentration, rather than in terms of an absolute amount of salt. Therefore, the claim language creates a measurement in terms of a proportion. *Id.*

Dr. Cummings asserts that a person of ordinary skill in the art “would understand the entire phrase ‘total concentration therein’ to refer to the complete set of information needed in order for an alleged infringer to determine whether he infringes or not.” *Id.* at ¶38. In such a proportion, “total salt” is the numerator, and “therein, which refers to “the allantoic fluid,” serves as the denominator. *Id.* at ¶37.

Dr. Cummings then refutes Microbix’s construction. He asserts that “a person of ordinary skill in the art would always consider concentration to refer to the volume of a fluid in its entirety, which is a known, measurable quantity.” *Id.* Further, Dr. Cummings stresses that concentration “does not have a temporal component, and is not generally tied to the occurrence or non-occurrence of a named event,” and

Even if it were possible to generate “pockets” of elevated concentration within a larger volume of allantoic fluid, there would be no way for a person of ordinary skill in the art to know the concentration in each pocket. Indeed, without knowing both the number of moles of salt (the numerator) and the total volume of allantoic fluid (the denominator), concentration cannot be measured. As such, a person of ordinary skill in the art would find it nonsensical to refer to a concentration of a sub-region found within a larger volume of a substance. That sub-region cannot be measured, and thus, concentration cannot be known.

Id. at ¶56.

As such, the extrinsic evidence indicates Microbix’s proposed construction imports a concept not associated with the art-understood meaning of concentration and that is not recited in the claims. Defendant’s proposed construction incorporates the art-understood concept of concentration into its construction with the inclusion of “total volume.”

In sum, the claim language, specification, and extrinsic evidence all support Defendant’s proposed construction. Accordingly, “total salt concentration therein” is construed as “total

amount of salt (in moles), whether added or intrinsic, in the total volume of debris-containing allantoic fluid after the addition of one or more salts.”

B. “salts”

Microbix proposed “any soluble inorganic or organic substance (having positively and negatively charged ions).” Doc. No. 68 at 10. Novartis proposed “a soluble inorganic or organic substance having positively and negatively charged ions that is the product of an acid-base reaction.” Doc. No. 70 at 26. The parties’ dispute is whether a “salt” is the product of an acid-base reaction.

At the January 15 hearing, Microbix conceded that salt, whether created in a lab or mined from the earth, is the product of an acid-base reaction. Microbix further stated that it was generally in agreement with Novartis’ proposed construction. Its only concern, was whether “the product of an acid-base reaction” could be construed as requiring the salt to be made in a laboratory before being used in the dissociation process. Novartis affirmed that its proposed construction created no such additional limitation. With an understanding that “product of an acid-base reaction” carried no additional time-based limitations, the parties agreed to Novartis’ proposed construction. Accordingly, “salts” is construed as, “a soluble inorganic or organic substance having positively and negatively charged ions that is the product of an acid-base reaction.”

CONCLUSION

For the foregoing reasons, the Court construes the claim language in this case in the manner set forth above. For ease of reference, the Court's claim constructions are set forth in a table attached to this opinion as Appendix A. The terms agreed to by the parties are attached to this opinion as Appendix B.

So ORDERED and SIGNED this 17th day of February, 2015.

APPENDIX A

The disputed terms of the '990 Patent are construed by the Court as follows:

Disputed Claim Terms	Construction
“total salt concentration therein”	total amount of salt (in moles), whether added or intrinsic, in the total volume of debris-containing allantoic fluid after the addition of one or more salts
“salts”	a soluble inorganic or organic substance having positively and negatively charged ions that is the product of an acid-base reaction

APPENDIX B

The parties have agreed to the following constructions:

Claim Terms	Agreed Construction
“dissociating virus from the debris” (claims 1 and 37)	Plain and ordinary meaning
“virus dissociated from debris” (claim 1)	Plain and ordinary meaning
“localize virus within the density gradient” (claims 6 and 37)	Plain and ordinary meaning
“allantoic fluid” (all claims)	“fluid substantially from the allantoic sac of an embryonated chicken egg”
“solubilized in the allantoic fluid” (claim 1)	“virus in solution”
“clarifying the allantoic fluid of step (a) by centrifugation” (claim 3)	“a recovery step using centrifugation to separate virus-containing supernatant from debris”
“sucrose density centrifugation” (claims 6 and 37)	“using a gradient of differing sucrose concentrations during centrifugation”